

DETAILED ACTION

Applicants' response of 3/22/2011 has been received and entered into the application file. Claims 1, 2, 4, 13, 20 and 25 have been amended. Claims 1-8 and 13-25 are pending in the insane application. All arguments have been fully considered, and are each addressed below, as appropriate. Rejections/objections not repeated herein have been withdrawn.

Election/Restrictions

Previously claims 25 and 26 were withdrawn as being directed to inventions which did not share unity of invention with the originally elected invention.

Applicants have traversed the withdrawal of claim 25 (as claim 26 is now cancelled) on the grounds that at least current claims 1 and 25 recite the same special technical features which distinguish the instant invention over the prior art. Furthermore, Applicants assert that searching claim 25 would not be unduly burdensome as claim 25 does not include any additional limitations which were not searched as part of the originally elected invention.

In response, it is first submitted that burden is not a requirement in determining propriety of restriction requirements in 371 applications, rather the only requirement is whether or not the presented claims have unity of invention. Previously claim 25 (and claim 26) were directed to products which were considered to be distinct from the product of claim 1, and because 37 CFR 1.475(e) only permits for one product to be present within a national stage application, the second and third products (i.e. the apparatuses of claims 25 and 26) were appropriately withdrawn.

However, at this point in prosecution claim 1 (representative of the originally elected group) has been substantially amended, and in its current form it is agreed that instant claim 1 and instant claim 25

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are directed to a single invention (i.e. share unity of invention), and thus claim 25 is being rejoined for examination at this point (claim 26 is now cancelled).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

RE: Rejection of claims under 35 USC 102(b) over Clark et al:

Applicants have traversed the rejection of record under 35 USC 102(b) over Clark et al on the grounds that the micromachined substrates of Clark et al only provide for organization of a single cell type into subassemblies (i.e. the grooves), whereas the instant claims require multiple cell types to be organized into subassemblies.

Applicants' arguments have been fully considered and are found persuasive in light of the amendments to the claims.

RE: Rejection of claims under 35 USC 102(e) over Vacanti et al:

Applicants have traversed the rejection over Vacanti et al on the grounds that claim 1 now requires that the micromachined surface structures include the nanotopographical features. Applicants assert the claims are limited such that the micromachined surface structures and the nanotopographical features are integral, not discrete, and thus the semi-permeable membranes of Vacanti (which are discrete

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from the support elements) do not read on the nanopotographic features of the instant claims.

Furthermore, claim 1 further requires the nanopotographic features to have a first a second portion, each of which are individually configured to enhance adhesion of a first and second cell type, respectively.

Applicants further traverse on the grounds that claim 13 requires micromachined surface structures having nanopotographic features superimposed thereon, which they assert Vacanti does not teach or suggest.

Applicants' remarks have been fully considered and are found persuasive in part. With regards to claim 1 the arguments, in combination with the claim amendments, are found persuasive to overturn the rejection of record. Vacanti does not teach the semi-permeable membrane being integral with the support structure, thus the micromachined surface structures do not include nanopotographic features. Furthermore, the semi-permeable membrane does not have different portions configured to separately enhance cell adhesion. Therefore the rejection is withdrawn over claims 1 and dependents thereof.

However, with regards to claim 13, it is respectfully submitted that Applicants have not fully described how they believe the claimed invention to differentiate over Vacanti et al. Unlike claim 1, claim 13 does not require the nanopotographical features to be integral to the micromachined surface, rather the claim requires the nanopotographical features to be *superimposed* on the micromachined surface. The semi-permeable membrane provided in the layered substrate of Vacanti is considered to be *superimposed* on the support element- noting that the semi-permeable membrane must attach at some point to the support element (as it cannot be hanging in space), thus it may be considered to be superimposed thereupon. Therefore the rejection of record stands over claims 13 and dependents thereof.

Furthermore, because the amendment to claim 1 has necessitated withdrawal of the lack of unity holding between the previously examined claims and claim 25, claim 25 is newly rejected over Vacanti. The modification of the rejection is considered to be necessitated by amendment.

Claims 13-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Vacanti et al (US 2007/0281353).

The applied reference has at least a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Vacanti et al disclose a three-dimensional system comprising at least two layers, wherein each layer comprises channels divided longitudinally into two compartments by a centrally positioned membrane, each compartment can comprise a different cell type. Each layer further comprises a support element, comprising a surface in which the channels are formed, and which defines the walls and floor of the channels (See Vacanti et al, ¶0050-0052). The system can be produced via a lithography process (See Vacanti et al, ¶0053-0055). The membrane which divides the channels into two compartments is preferably porous, the pores are nanosized (See Vacanti et al, ¶0085).

The support element is considered to read on a substrate having micromachined surface structures provided thereon. The nanoporous membrane, provided on the support element, is considered to read on nanotopographic features superimposed on the support element. The orientation of the membrane is such that it organizes multiple cell types into desired subassemblies (i.e. separates vascular cells from parenchymal cells). The nanoporous membrane is also appropriately considered to be present *within* the micromachined surface structures, noting that the membrane is positioned within the microchannels formed by the surface structures. The fact that the membrane separates the different cell types the membrane is considered to have portions (i.e. sides) which necessarily 'select' first and second cell types (i.e. the cells retained on either side of the membrane).

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Different cell types, including combinations of hepatocytes and fibroblasts, are specifically taught to be provided within the compartments of a single channel (See Vacanti et al, claim 35). A pumping means can further be included in the device to circulate fluid through the device (See Vacanti et al, claim 36). The system can further comprise lines in fluid communication for excretion removal (See Vacanti et al, ¶0106). Therefore the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

RE: Rejection of claims under 35 USC 103(a) over Clark et al:

For the reasons discussed above, the rejections based on Clark et al have been withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In*

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re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

RE: Rejection of claims over copending application 10/557,081:

Applicants have filed a terminal disclaimer over copending application 10/557,081. The terminal disclaimers have been approved and recorded, as such the obviousness-type double patenting rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

RE: Rejection of claims under 35 USC 112, second paragraph, as being indefinite:

The amendments to the claims obviate the previous grounds of rejection thereto. However, the claim amendments have necessitated the following new grounds of rejection:

New Grounds of Rejection, Necessitated by Amendment:

Claims 2-8 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-8 recite the limitation "The substrate as recited in claim [1]" or "A substrate as recited in claim [1]". There is insufficient antecedent basis for this limitation in the claims, as claim 1 has been amended to define a tissue engineered structure. It would be remedial to simply amend the dependent claims to refer to "The structure as recited in claim [1]".

In claim 25 it is unclear what is meant by the nanotopographical features having portions configured "to select" for first or second cell types, select how? on a physical basis? is an actual selection done? Or do the nanotopographical features simply facilitate adhesion of one type of cell to a greater degree than a different type of cell? Clarification is required.

New Ground of Rejection, Necessitated by Amendment:

Claim Rejections - 35 USC § 112

The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Claim 3 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of the a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 3 requires the nanotopographic features (of claim 1) to facilitate adhesion of one or more cell types; however, claim 1 as currently amended already recites that the nanotopographic features are configured to enhance adhesion of various cell types. Thus claim 3 no longer further limits the parent claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651